

REMARKS

Introductory Comments:

Claims 1, 2 and 4-26 were examined in the Office Action under reply and rejected under (1) 35 U.S.C. §102; and (2) 35 U.S.C. §103. These rejections are respectfully traversed as discussed more fully below.

Applicant notes with appreciation the rejoinder of claim 2 with the claims being examined.

Formal Matters:

Applicant is submitting a Sequence Listing and new Formal Drawings herewith.

Overview of the Above Amendments:

The specification has been amended to insert sequence identifiers.

Claims 4, 5 and 15 have been cancelled herein and the substance thereof included in amended claims 1 and 13. Claims 6, 7 and 16-18 have been amended to depend from non-cancelled claims.

Cancellation of claims 4, 5 and 15 and amendment of claims 1, 6, 7, 13 and 16-18 is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant expressly reserves the right to file one or more continuing applications hereof containing the canceled or unamended claims.

Rejections Under 35 U.S.C. §102:

Claims 1, 2, 4-10 and 13-26 were rejected under 35 U.S.C. §102(a) as anticipated by Kay et al., *Nat. Genet.* (March 2000) 24:257-261 ("Kay") as evident by U.S. Patent No. 6,200,560 to Couto et al. ("Couto"). However, the inventor of the present application, Katherine A. High, is a coauthor on Kay et al. and the relevant portions of

Kay et al. describe applicant's own work. To evidence this, applicant is submitting a Declaration of Katherine A. High, pursuant to *In re Katz*. Thus, this basis for rejection has been overcome. Withdrawal thereof is respectfully requested.

Claims 1, 2, 4, 8-14, 21 and 24 were rejected under 35 U.S.C. §102(e) as anticipated by Couto. Applicant notes that claims 5 and 15 were not subject to this rejection. The recitations of claims 5 and 15 have been inserted into independent claims 1 and 13, respectively. All remaining claims either directly or ultimately depend from claims 1 and 13. Thus, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

Claims 1, 2, 4-10 and 13-26 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,093,392 to High et al. ("High"). The Office correctly notes that High has a common inventor with the present application and that this reference can be overcome by eliminating High by means of a Declaration pursuant to 37 CFR §1.132. Applicant is providing a Declaration of Inventorship that satisfies the requirements of MPEP §706.02(k)(C). Thus, the High patent is not "an application for patent by another" and is therefore not properly citable art against the present application. Withdrawal of this basis for rejection is therefore respectfully requested.

Rejections Under 35 U.S.C. §103(a):

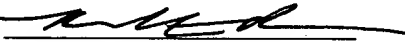
Claims 1, 11 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kay in view of Couto. As explained above, Kay is not properly citable art against the present claims. Moreover, claim 1 now incorporates the recitations of claim 5 which was not subject to this rejection. Claims 11 and 12 both ultimately depend from claim 1. Accordingly, withdrawal of this basis for rejection is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims define a patentable invention. Accordingly, a Notice of Allowance is believed in order and is respectfully requested. If the Examiner notes any further matters which he believes may be resolved by a telephone interview, he is encouraged to contact the undersigned by telephone at 650-493-3400.

Respectfully submitted,

Date: 10/28/03

By: 
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Atty Dkt No. 0800-0024
PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

KATHERINE A. HIGH

Confirmation No.: 5537

Serial No.: 09/880,702

Group Art Unit: 1635

Filing Date: June 13, 2001

Examiner: B. Whiteman

Title: METHODS FOR ADMINISTERING RECOMBINANT ADENO-
ASSOCIATED VIRUS VIRIONS TO HUMANS PREVIOUSLY
EXPOSED TO ADENO-ASSOCIATED VIRUS

DECLARATION OF INVENTORSHIP

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

I, Katherine A. High, hereby declare as follows:

1. I have reviewed U.S. Patent No. 6,093,392, entitled "METHODS AND COMPOSITIONS FOR USE IN GENE THERAPY FOR TREATMENT OF HEMOPHILIA" on which I am a coinventor. I have also reviewed the claims pending in the present application.

2. I understand the Patent Office is relying on U.S. Patent No. 6,093,392 in the current Office Action as teaching the claimed invention. I am the original inventor of the subject matter claimed in the above-identified application and of the unclaimed subject matter disclosed in U.S. Patent No. 6,093,392 relied upon by the Patent Office. Roland W. Herzog who is listed as a coinventor on U.S. Patent No. 6,093,392 and is not named as an inventor on the present application did not conceive of the subject matter claimed in the present application.

Atty Dkt No. 0800-0024
USSN: 09/880,702
PATENT

3. I declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 10/15/03

Katherine A. High
Katherine A. High



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Title: METHODS FOR ADMINISTERING RECOMBINANT ADENO-
ASSOCIATED VIRUS VIRIONS TO HUMANS PREVIOUSLY
EXPOSED TO ADENO-ASSOCIATED VIRUS

DECLARATION OF KATHERINE A. HIGH

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

I, Katherine A. High, hereby declare as follows:

1. I am the inventor of the subject matter disclosed and claimed in the above-referenced patent application, U.S. Serial No. 09/880,702, filed June 13, 2001, claiming the benefit of U.S. Provisional Application Serial No. 60/211,066, filed June 13, 2000. I am also a coauthor on Kay et al., "Evidence for Gene Transfer and Expression of Factor IX in Haemophilia B patients treated with an AAV vector" *Nat. Genet.* (2000) 24:257-261 ("Kay et al.").

2. The portions of Kay et al. relevant to the present invention originated from the me. The noninventor coauthors on Kay et al., namely, Kay, Manno, Ragni, Larson, Couto, McClelland, Glader, Chew, Tai, Herzog, Arruda, Johnson, Scallan, Skarsgard and Flake, did not conceive of the subject matter claimed in the above-identified patent application and are not coinventors thereof.

Atty Dkt No. 0800-0024
USSN: 09/880,702
PATENT

3. I declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 10/15/03

Katherine A. High
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